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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,736	05/18/2005	Junichi Inagawa	B 520	9426

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EXAMINER	
HOBBS, LISA JOE	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,736	INAGAWA ET AL.	
	Examiner	Art Unit	
	Lisa J. Hobbs	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07/11/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 12/02/2005.

Election/Restrictions

Claim16 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected method, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 07/11/2007.

Claim Status

Claims 1-15 and 18-20 are currently under examination. Claims 4, 9, 11-13, 15, 18 and 20 were amended by a preliminary amendment filed 05/18/2005.

Claim Objections

Claim1 is objected to because of the following informalities: the second line recites "at last one" tag, which should apparently be "at least one" tag. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 2001/72458) in view of Bosman et al. (WO 1999/00670), Barner et al. (US 5986066), Badley et al. (US 6294391) and Nelson et al. (US 5955729). Wagner et al. teach heterofunctional cross linking reagents, protein labeling reagents, protein conjugates and their compositions, support-bound cross linking groups, modified supports and protein arrays for site specific binding of proteins, they teach techniques for attaching a biomolecule (a protein) containing a tag by binding sites for the biomolecule tag and for covalently attaching a biomolecule to activated reactive groups (support-bound cross linking groups) to a solid support. Barner et al. teach cross-linking molecules, which molecules will biologically recognize target molecules, to a solid phase using carrier molecules. Bosman et al. teach methods of covalently immobilizing biomolecules by means of a His-tag and using a substrate that biologically recognizes the His tag. Badley et al. teach methods of detecting the presence of an analyte of interest in a sample, the method comprising the steps of: providing a binding partner reversibly immobilized on a solid support, said binding partner having binding specificity for the analyte; contacting the sample with the solid support; specifically displacing the binding partner from the

solid support in response to the presence of the analyte of interest in the sample, said displacement causing a reduction in the mass of material immobilized on the solid support, thereby generating a detectable change in a mass-dependent property of the solid support; and detecting said change, while Nelson et al. teach detection of analytes using surface plasmon resonance.

Wagner et al. teach that it is known to attach a protein to a solid support by associating a protein containing a tag with a protein tag binder, see page 6, lines 3-10 (claims 1, 12, 18, and 20); they also disclose a method for covalently attaching a protein to the surface by linking groups (claim 2). Wagner et al. also teach the use of an amino group from the biomolecule and a carboxyl group of the sensor chip to create a covalent bond (claim 3). As well, Barner et al. explicitly state in columns 3 and 4 that reactive functional groups, such as COOH or NH_2 are well-known for use as covalent attachment points for immobilizing biomolecules (claims 2-3).

Additionally, Wagner et al. teach naturally binding molecules (claim 11), such as antigen/antibody recognition epitopes, as protein-tag binders. On page 13 they teach His tags (claims 9-10). However, they do not teach details of His tag antibody and antigen reactions. Bosman et al. teach detailed methods of using His tags and His tag antibodies, see entire document, including the complexing of glycoproteins to metal affinity resin on page 3 (claim 19).

At page 26, Wagner et al. teach the introduction of introduce histidine tags into the protein (claim 4) and then the binding of the protein to a sensor chip coated with nitrilotriacetic acid (NTA) through Ni2+ (claims 4-7). Wagner et al. do not teach the use of iminodiacetic acid

(IDA), however it is taught by Bosman et al., page 3, that IDA/Ni2+ can be used as an alternative to NTA in His tag immobilization (claim 8).

Wagner et al. do not specifically teach low molecular weight compound binding (claims 13 and 15), however they, Barner et al., and Bosman et al., do describe multiple binding substituents, including a statement by Bosman et al. that the invention is "to simultaneously provide a universal detection method for biomolecules that contain a His tag", page 5, and Wagner et al. teach protein-protein, protein-nucleic acid, protein-drug, and protein-ligand interactions, see page 2, which encompasses a large range of molecular weights.

The use of surface plasmon resonance to measure and detect biomolecules and analytes of interest (claim 14) is known in the art, as described by Nelson et al., see entire document, while Badley et al. specifically teach methods of detecting the presence of an analyte of interest in a sample, the method comprising the steps of: providing a binding partner reversibly immobilized on a solid support, said binding partner having binding specificity for the analyte; contacting the sample with the solid support; specifically displacing the binding partner from the solid support in response to the presence of the analyte of interest in the sample, said displacement causing a reduction in the mass of material immobilized on the solid support, thereby generating a detectable change in a mass-dependent property of the solid support; and detecting said change, paragraph 23, using "a number of mass-dependent properties which can be detected, for example, by acoustic wave or evanescent wave type sensors, or by surface plasmon resonance (SPR) detectors, all of which are known in the art".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Wagner et al. with Barner et al., Bosman, et al., Badley et

al., and Nelson et al. in order to achieve the invention as claimed in the claims under examination. As demonstrated above, methods for the immobilization of biomolecules involving covalent binding of substituents by chemical groups or by antibody/antigen binding, assisted by other chemicals, using components naturally present or added to the molecules as needed, were known in the art and the claims, as presented, are rendered obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/17/07

Lisa J. Hobbs
Primary Examiner
Art Unit 1657

ljh